JUN 1 4 2001

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K002543

1. **Submitter's Identification:**

San Up S.A.
Ruta 8 #2967 (1650)
San Martin
Buenos Aires, Argentina 1650
Mr. Jorge Shemi
President

Date Summary Prepared:

August 2, 2000

2. **Name of the Device:**

SanUp S.A. Compact Ultrasonic Nebulizer, Model 3060

3. **Predicate Device Information:**

The ICEL Ultrasonic Nebulizer Model PU 12300 Air, K#9722371 and ICEL Ultrasonic Nebulizer PU 12300, K#951254, Brasamerica Medical Equipment, Inc.

4. **Device Description:**

The San Up S.A. Compact Ultrasonic Nebulizer, Model 3060 has been developed with the patient's necessities in mind for the delivery of spray liquids in aerosol form into gases directly to the patient for breathing for use by the adult and pediatric populations.

This hand-held ultrasonic generator unit includes a sealed water reservoir to couple the ultrasonic energy to the medication cup. The hand-held unit also includes a small rotary fan that draws room air through a filter and propels the nebulized medication to the outlet port. Face masks, a mouth tube, and nasal prongs are provided that connect to the outlet port. The generator unit is powered by 20 VDC, supplied from a plug-mounted AC adapter that connects to line power. The generator will operate for 3 minutes at a time, stopping for the user to either confirm that there is sufficient medication for continued

operation or to add more medication to the cup. The nebulizer is housed in a white plastic case with dimensions of 83.5 mm x 169 mm x 60 mm and weighing 260 grams. It is powered from 115 VAC, 60 Hz, through a Model SS48-200-0500D "power cube" that plugs into a wall outlet and provides approximately 20 VDC to the handheld nebulizer.

In addition to the above information, the San Up S.A. Compact Ultrasonic Nebulizer, Model 3060 operates at an ultrasonic frequency of 2.5 MHz with a particle size range of 1.5-5.7 microns for greater respiration mass. The disposable medication cups have 8 ml capacity, and an average of 0.5ml/minute/minimum nebulization rate.

5. **Intended Use:**

This ultrasonic nebulizer is intended to spray liquids in aerosol form into gases that are delivered directly to the patient for breathing. It is portable and compact in design for use by both the adult and pediatric populations.

6. **Comparison to Predicate Devices:**

Differences between the two (2) devices is minimal. The ICEL Nebulizer is lighter in weight and smaller in size. The electrical requirements, power consumption, ultrasonic operating frequency, particle size range and nebulization rate are similar in between both devices. The San Up S.A. power source is an AC adapter only.

Air Flow for the San Up S.A. devices is built in the nebulizer body, whereas airflow is present in the US 3000 module for the ICEL PU 12300 device. The San Up S.A. device does not contain an intensity control/indicator mechanical switch as the ICEL device.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the San Up s.a. Compact Ultrasonic Nebulizer, Model 3060 in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following testing was conducted by CITECH using three (3) sampleS of the San Up s.a. device:

a. Normal operation under all combinations of the following:
   - Temperature of +5°C, +20°C, and +40°C (the last at high humidity)
   - Line voltage of 95, 115, and 132 V
b. Storage at -20°C and +60°C
c. Fluid spill resistance
d. Maximum surface temperature

e. Sinusoidal vibration
f. Impact (drop) resistance
g. Leakage current and dielectric withstand (electrical safety)

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was CITECH's conclusion that the San Up s.a. Compact Ultrasonic Nebulizer, Model 3060, tested met all relevant requirements of the aforementioned test.

In addition, the following testing was conducted by CITECH for EMC Testing:

a. Radiated and Conducted Emissions, per CISPR 11
b. Magnetic Field Emission, per MIL-STD-462D, Method RE101
c. Fast surges, per Reviewer Guidance document
d. Electrostatic Discharge, per IEC 801-2

(h) In addition a Nebulizer Characterization Study was performed with passing results. The test was conducted in accordance with the Federal Good Laboratory Practices 921 CFR Part 58 (FDA) or 40 CFR Part 160 (EPA).

8. Discussion of Clinical Tests Performed:

No clinical tests were performed and none are submitted with this 510(k) submission.

9. Conclusions:

Based upon non-clinical testing performed and the results of such testing, we have demonstrated that the San Up S.A. Compact Ultrasonic Nebulizer, Model 3060 is as safe and effective and performs as well as our predicate device cited in this 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 4 2001

Ms. Susan D. Goldstein-Falk
San Up s.a.
c/o MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, NY 11021

Re: K002543
Compact Ultrasonic Nebulizer, Model 3060
Regulation Number: 868.5630
Regulatory Class: II (two)
Product Code: 73 CAF
Dated: June 6, 2001
Received: June 8, 2001

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

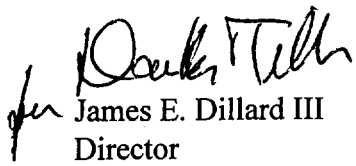
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002543

Device Name San Up s.a. Compact Ultrasonic Nebulizer Model 3060

Indications For Use:

This ultrasonic nebulizer is intended to nebulize inhalable drugs that are delivered directly to the patient for breathing for use by both the adult and pediatric populations.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002543

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)